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09/782,130	02/12/2001	Vic C. Knauf	16518.052	2541

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

16

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/782,130

Applicant(s)

KNAUF ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

The effective filing date for the instantly claimed application, drawn to seed-specific promoters and their use, is 31 July 1986, the filing date of parent application Serial No. 06/891,529 which was the earliest parent to teach such a promoter.

Claims 17-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,420,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs containing a seed-specific promoter and plant cells containing them as claimed in the patent to obtain the methods of using DNA constructs containing a seed-specific promoter to obtain transformed plant cells and plants containing them as claimed in the instant application.

Claims 17-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent 5,608,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the plants and seeds containing DNA constructs containing a seed-specific promoter for seed-specific expression of heterologous genes as claimed in the patent to obtain the methods of using DNA constructs containing a seed-specific promoter to obtain transformed plant cells and plants containing them as claimed in the instant application.

Claims 17-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent 5,981,839.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the plants and seeds containing DNA constructs containing a seed-specific promoter for seed-specific expression of heterologous genes and transformed plant cells and plants containing them as claimed in the patent to obtain the methods of using DNA constructs containing a seed-specific promoter to obtain transformed plant cells and plants containing them as claimed in the instant application.

Claims 17-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,281,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the methods of using DNA constructs containing a seed-specific promoter to obtain transformed plant cells and plants containing them, as claimed in the patent, to obtain the methods of using DNA constructs containing a seed-specific promoter to obtain transformed plant cells and plants containing them, as claimed in the instant application.

Claims 17-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-29, 62-130, 133-138 of copending Application No. 09/574,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the DNA constructs comprising a seed-specific promoter, methods of their use to produce transformed plants which

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express heterologous genes in a seed-specific manner, and the resultant transformed plants, as claimed in the copending application; to obtain the methods of using DNA constructs comprising a seed-specific promoter to obtain transformed plants as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the use of seed-specific promoters from *Brassica* for seed-specific gene expression, transcription, or phenotypic alteration, including the napin, acyl carrier protein, and EA9 gene promoters; does not

reasonably provide enablement for claims broadly drawn to the use of any promoter or any regulatory sequence from any plant species to effect seed-specific gene expression, transcription or phenotypic alteration, or any cruciferin promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only demonstrates the use of three seed-specific promoters from the same genus of the same plant family for the seed-specific expression of heterologous genes. No guidance is presented regarding the identification, isolation, or evaluation of other seed-specific promoters from any other plant genus or family for their ability to effect seed-specific heterologous gene expression. In addition, no guidance is provided in the instant specification regarding the isolation of any cruciferin gene, the isolation of its corresponding promoter, and the evaluation of the putative cruciferin promoter for seed-specific expression of heterologous genes. In contrast, the claims are broadly drawn to any seed-specific promoter or regulatory sequence from any plant of any species, genus or family, (including cereal plants such as corn or oats, leguminous plants such as soybean or alfalfa, palms such as coconut or date, lily family plants such as onions or lilies, squash plants such as cucumber and pumpkin, and conifers such as pine or sequoia) or from any cruciferin gene, which would be sufficient to effect seed-specific gene expression.

Furthermore, tissue-specific gene expression could be the result of a variety of complex factors other than a tissue-specific promoter immediately upstream of the

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structural gene. Such alternate factors include distant genes encoding regulatory proteins, activator/operator/repressor systems, far upstream or downstream enhancer elements, changes in the phosphorylation of transcriptional proteins, export of mRNA from DNA found in other organelles or tissues, transposable elements, and post-transcriptional controls such as alternative RNA splicing (see, e.g., Garland Publishing, *Molecular Biology of the Cell*, pages 553-569; 588-597, and 606-607).

Thus, multiple attempts to isolate the putatively tissue-specific promoters associated with a multitude of genes encoding tissue-specific gene products could prove unsuccessful.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate a multitude of non-exemplified promoter types or other types of regulatory sequences for their ability to effect seed-specific gene expression. Undue experimentation would have also been required to identify and isolate a multitude of non-exemplified cruciferin genes and any putative promoter associated therewith, and to evaluate said promoters for the ability to effect seed-specific heterologous gene expression.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

See also In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein.

Claims 17-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification only describes three seed-specific promoters from the same genus of the same plant family for the seed-specific expression of heterologous genes. No guidance is presented regarding the identification, isolation, or characterization of other seed-specific promoters from any other plant genus. In addition, no guidance is provided in the instant specification regarding the isolation of any cruciferin gene, the isolation of its corresponding promoter, and the evaluation of the putative cruciferin promoter for seed-specific expression of heterologous genes. In contrast, the claims are broadly drawn to any seed-specific promoter or regulatory sequence from any plant of any species, genus or family, (including cereal plants such as corn or oats, leguminous plants such as soybean or alfalfa, palms such as coconut or date, lily family plants such as onions or lilies, squash plants such as cucumber and pumpkin, and conifers such as pine or sequoia) or from any cruciferin gene, which would be sufficient to effect seed-specific gene expression.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a



precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description

Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zambryski et al. taken with Sengupta-Gopalan et al.

The claims are broadly drawn to a method of transforming a dicotyledonous plant with a DNA construct comprising a seed-specific promoter, such as a seed storage protein promoter, operably linked to a heterologous gene for the expression of the heterologous gene product in a seed-specific manner.

Zambryski et al. teach a method of tumor-free transformation comprising tobacco plant infection with tumor gene-free Agrobacterium strains containing genes for opine synthase and antibiotic resistance under the control of a plant-expressible promoter, and suggest the wide use of this method for the introduction of heterologous genes into plants (see, e.g., paragraph bridging pages 2143 and 2144; page 2145, column 1, second full paragraph; paragraph bridging pages 2148 and 2149; page 2149, column 1).

Zambryski et al do not teach the use of seed-specific promoters.

Sengupta-Gopalan et al. teach the function of the seed-specific phaseolin promoter in seeds of a heterologous tobacco plant, identify the exact correspondence of

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phaseolin cDNA and phaseolin mRNA in transformed tobacco cells (from which the transcription start site of the native phaseolin gene could have been deduced, thereby enabling deduction of the upstream promoter region), and suggest the use of the technique for the obtention of tissue-specific expression of a variety of heterologous genes in a variety of crop plants (see, e.g., page 3321, column 1; page 3322, column 1, top paragraph; page 3324, column 2, top paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation taught by Zambryski et al. and to modify that method by incorporating the phaseolin promoter taught by Sengupta-Gopalan et al., as suggested by Zambryski et al. and Sengupta-Gopalan et al. Choice of transformable and regenerable plant species or gene of interest (such as an enzyme-encoding gene or an antisense RNA-encoding gene) would have been the optimization of process parameters. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 20, 33, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zambryski et al. taken with Sengupta-Gopalan et al. as applied to claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 above, and further in view of Pedersen et al.

The claims are broadly drawn to methods of transforming soybean plants with a seed-specific promoter for seed-specific gene expression.

Zambryski et al. taken with Sengupta-Gopalan et al. teach the method of tumor gene deletion and gall-free Agrobacterium-mediated transformation for the expression of heterologous genes under the control of seed-specific promoters as discussed above, but do not teach soybean transformation.

Pedersen et al. teach the injection of soybean plants with Agrobacterium to effect transformation (see, e.g., page 201, column 2, third full paragraph; page 203, column 1, bottom paragraph, Figure 4).

It would have been obvious to one of ordinary skill in the art to utilize the method of tumor gene deletion and gall-free Agrobacterium-mediated transformation for the expression of heterologous genes under the control of seed-specific promoters taught by Zambryski et al. taken with Sengupta-Gopalan et al., and to modify that method by incorporating the soybean-infecting Agrobacterium plasmid taught by Pedersen et al., given the recognition by those of ordinary skill in the art that each would have continued to function in its known and expected manner, and the recognition of the benefits of transforming a wide variety of plant species including soybean as suggested by Sengupta-Gopalan et al. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al.

Hall et al. teach the Agrobacterium-mediated transformation of sunflower, alfalfa and tobacco cells with a heterologous phaseolin promoter and phaseolin structural gene, wherein expression of the phaseolin gene is highly regulated and seed-specific in the native bean, wherein intronless phaseolin genes were also constructed, wherein deletions of the tumor genes on the Ti plasmid were performed, and wherein whole tobacco plants were recovered which expressed high levels of the protein in the seed in the same pattern in which it was expressed in the native bean (see, e.g., column 9, lines 55-68; column 10, lines 1-16 and 57-59; column 19, lines 30-67; columns 20-21; column 22, lines 1-41; column 24, lines 9-61; columns 28-31, especially column 29, lines 1-5 and 60-68). Hall et al also teach phaseolin cDNA from which the transcription initiation region of the native gene, and the upstream promoter, could have been deduced if desired (see, e.g., column 19, lines 57-67; column 20, lines 1-7). Hall et al. also teach the transformation of alfalfa cells with a chimeric gene comprising the nopaline synthase promoter and a gene encoding the neomycin phosphotransferase enzyme, and suggest the transformation of a variety of plants with a plant gene-derived promoter such as the phaseolin promoter and a variety of structural genes such as genes conferring disease resistance, herbicide resistance, or flavor components (see, e.g., column 24, lines 9-61; column 10, lines 45-59; and claims 11-30).

Hall et al. do not explicitly teach a chimeric gene construct comprising the phaseolin promoter and a heterologous structural gene.

Sengupta-Gopalan et al. teach that a heterologous gene comprising the phaseolin promoter and phaseolin structural gene is expressed in a highly seed-specific

manner in the heterologous species tobacco following Agrobacterium-mediated transformation, and that the phaseolin promoter contains all of the necessary components for seed-specific expression; and suggest the value of tissue-specific heterologous gene expression in transformed plants (see, e.g., page 3320, Abstract; page 3321, Table 1 and column 1; page 3323, column 2, third full paragraph; page 3324, column 2, top paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the phaseolin promoter which functions in a variety of heterologous plant species as taught by Hall et al. for the seed-specific expression of a variety of heterologous genes such as the neomycin phosphotransferase gene taught by Hall et al. in a variety of heterologous plants, as suggested by Hall et al. and Sengupta-Gopalan et al. Choice of heterologous plant species or heterologous structural gene would have been the optimization of process parameters. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 20, 33, 38 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hall et al. (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al. as applied to claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 above, and further in view of Zambryski et al. taken with Pedersen et al.

Hall et al. taken with Sengupta-Gopalan et al. teach the transformation of a variety of plant species including alfalfa with a tumor gene-deleted Agrobacterium tumefaciens vector comprising the phaseolin promoter and heterologous structural gene

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for seed-specific gene expression as discussed supra, but do not teach soybean transformation.

Zambryski et al. teach a method of tumor-free transformation comprising plant infection with tumor gene-free Agrobacterium strains containing genes for opine synthase and antibiotic resistance under the control of a plant-expressible promoter, and suggest the wide use of this method for the introduction of heterologous genes into plants (see, e.g., paragraph bridging pages 2143 and 2144; page 2145, column 1, second full paragraph; paragraph bridging pages 2148 and 2149; page 2149, column 1).

Pedersen et al. teach the injection of soybean plants with Agrobacterium to effect transformation (see, e.g., page 201, column 2, third full paragraph; page 203, column 1, bottom paragraph, Figure 4).

It would have been obvious to one of ordinary skill in the art to utilize the method of tumor gene deletion and gall-free Agrobacterium-mediated transformation for the seed-specific expression of heterologous structural genes under the control of the phaseolin promoter in a variety of plant species including alfalfa as taught by Hall et al. taken with Sengupta-Gopalan et al., and to modify that method by incorporating the tumor deletion and whole plant regeneration taught by Zambryski et al. and the soybean-infecting Agrobacterium plasmid taught by Pedersen et al., given the recognition by those of ordinary skill in the art that each would have continued to function in its known and expected manner, and the recognition of the benefits of transforming a wide variety of plant species including soybean, as suggested by Hall et



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al. taken with Sengupta-Gopalan et al. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Claims 48-49 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggested an isolated cruciferin promoter or its use to transform plants.

No claim is allowed.

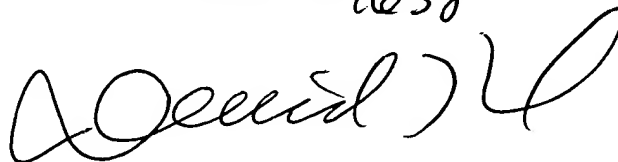
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 8, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and title.